

REMARKS

Applicants courteously solicit a favorable reconsideration and allowance of Claims

1-9.

Applicants acknowledge with appreciation the Examiner's favorable reconsideration of certain earlier rejections under 35 U.S.C. § 102(b) and 103(a) as indicated in the May 23, 2007 Office Action, page 2, paragraph No. 1.

**1. Applicants respectfully solicit the Examiner's favorable reconsideration of rejections of Claims 1-5 under 35 U.S.C. § 102 (b) over Nishimura et al. (Eur. J. Appl. Physiol. 87, 337-342, 2002).**

Applicants respectfully request withdrawal of the rejection of Claims 1-5 under 35 U.S.C. § 102(b) over Nishimura.

The Office Action cites Nishimura and rejects Claims 1-5 of the present invention and offers the following theses (emphasis added).

"Nishimura discloses a vascularization therapy comprising steps of: immersing right forearm in carbon dioxide-rich water (1,000 ppm) that was maintained at a temperature of 34°C. The CO<sub>2</sub> bathing was performed consecutively for five days. As a control study, subjects bathed in fresh water at 34°C under the same conditions (*see* abstract). Tympanic temperature (T<sub>ty</sub>) was significantly lowered during CO<sub>2</sub> bathing, cutaneous blood flow in the immersed right forearm was significantly increased greatly, and during CO<sub>2</sub> bathing reached 200-250% of the pre-bathing control value. The rate of increase was greatest during the first 10 min of CO<sub>2</sub> bathing, and then tended

to lessen (*see* page 339). And also the results of the study discloses that CO<sub>2</sub> bathing produces a decline in core temperature, an increase in cutaneous blood flow, and an elevation of the score on thermal sensation. **In CO<sub>2</sub> bathing, increased cutaneous blood flow due to cutaneous vasodilation can facilitate the formation of new blood vessels of an affected site.**

\* \* \*

It is noted that the intended use “vascularization” recited in the claims are considered, but the claims are properly included in this rejection because a recitation of the intended use of claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.”

Applicants respectfully traverse this rejection for the following reasons.

Nishimura does not teach or even suggest the vascularization therapy claimed in the present invention.

Nishimura does not disclose anything about vascularization as recited in Claims 1-5 of the present invention. The term “vascularization” recited in the claims refers, as rightly described by the Office Action in the above highlighted sentence, the “formation of new blood vessels.” *See, e.g.,* Stedman’s Medical Dictionary, 27<sup>th</sup> Edition, page 1932 (2000) (“vascularization” means “[t]he formation of new blood vessels”).

On the other hand, the term “vasodilation” refers to the widening of blood vessels resulting from relaxation of the muscular wall of the vessels and what widens is actually the diameter of the interior (the lumen) of the vessel. *See, e.g., Stedman’s Medical Dictionary, 27<sup>th</sup> Edition, page 1933 (2000)* (“vasodilation” means “[w]idening of the lumen of blood vessels”).

Nishimura might *arguendo* teach immersion of a subject’s right forearm (a healthy male) in carbon dioxide-rich water (1,000 ppm) that was maintained at a temperature of 34°C and reports the increase in cutaneous blood flow possibly due to cutaneous vasodilation as a result of immersing. However, an alleged “increase in cutaneous blood flow due to cutaneous vasodilation” is not the “formation of new blood vessels”, i.e., not vascularization. (Nishimura would not support an inherency rejection.) Nishimura does not immerse the affected site of a peripheral blood vessel in carbonated warm water having a carbon dioxide concentration of at least 700 ppm and a temperature of 33 to 42°C. In fact, in Nishimura, healthy males are the “subjects” immersed in carbonated warm water. Accordingly, it is rather problematic at best to consider Nishimura either intended immersion for vascularization therapy or was even contemplating – hinting at - such actual use.

The above physiological effects of vasodilation and vascularization are clearly distinct from each other. There is no objective evidence presented in the Office Action to link the two. Indeed, Nishimura does not teach or even suggest the term “vascularization” or anything about the “formation of new blood vessels.”

The passage the Office Action quoted from Nishimura actually reads “In CO<sub>2</sub> bathing, increased cutaneous blood flow due to cutaneous vasodilation may facilitate heat transfer from the body to water” (page 340, second column, lines 12-14) which is unrelated to the “formation of new blood vessels.” *See, e.g., In re Hedges*, 228 USPQ 685, 686 (Fed. Cir. 1985 (an extremely strained interpretation of the reference which would only be made by hindsight, rejection reversed)).

Lastly, The Office Action rejects Claims 1-5 of the present invention by Nishimura under 35 U.S.C. § 102 (b) rather than 35 U.S.C. § 112, 6<sup>th</sup> paragraph, and thus Applicants fail to see the connection between the above rejection with the present invention. Applicants respectfully request reconsideration – or at least an explanation - of the rejection in the Office Action insofar as the rejection mentions “intended use” with a direct quotation from 35 U.S.C. § 112, 6<sup>th</sup> paragraph. The latter “means-plus-function” provisions should only apply to apparatus, article, and composition claims drafted in means plus function format. The present invention is claiming vascularization therapy and is not claiming an apparatus, an article, or a composition in means plus function format.

In summary, Nishimura does not teach or even suggest the vascularization as recited in Claims 1-5 of the present invention. Moreover, the intention to use their work for a therapy cannot be found in Nishimura and much more detailed work is clearly needed for that purpose even if there was such an intention. In other words, the present invention is clearly patentably distinguished from Nishimura.

**Applicants respectfully solicit the Examiner's favorable reconsideration of the rejection of Claims 1-9 as obvious under 35 U.S.C. § 103(a) over Ritter et al. (US No. 6,086,863) in view of the Nishimura et al. reference.**

Applicants respectfully request withdrawal of the rejection of Claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Ritter in view of Nishimura.

Neither Nishimura nor Ritter teaches or even suggests the "vascularization therapy" recited in the Claims of the present invention.

The Office Action cites Ritter and Nishimura and rejects the present invention apparently under this rationale:

"Ritter discloses a therapeutic compositions of microspheres for application to wound and/or lesions for accelerating wound healing and muscle regeneration. The therapeutic composition further contains pharmacologic agents or biologics that accelerate the wound healing process (*see* abstract). Essentially, all wound healing involves the repair of replacement of damaged tissues including but not limited to skin, muscle, neurologic tissues, bone, soft tissue, internal organs or vascular tissue (*see* column 1, lines 19-25, which would encompass "vascularization therapy" as claimed). Most of basic research in angiogenesis has concentrated on the various steps involved in blood vessel growth and in identifying molecules that either enhance or inhibit such processes. The therapeutic composition includes genetically engineered stromal cells (e.g. fibroblasts with or without other cells and/or

elements found in loose connective tissue taken from the subject, including but not limited to, endothelial cells, pericytes, macrophages, monocytes, plasma cells, mast cells, adipocytes, etc.) which express a gene product beneficial for successful and/or improved wound healing process. The therapeutic composition includes microspheres and one or more of agents selected from the group consisting of anti-inflammatory, antibiotic, antiseptic, antifungal, analgesic, astringent agent and collagen for healing the injured tissue...”

“Ritter meets the claim limitations as described above but fails to include carbonated warm water... . However, Nishimura discloses a vascularization therapy comprising steps of: immersing right forearm in carbon dioxide-rich water (1,000 ppm) that was maintained at a temperature of 34°C.”

“It would have been obvious to one of ordinary skill in the art to modify the therapeutic composition disclosed by Ritter to include carbonated warm water having a carbon dioxide concentration of at least 700 ppm, because Nishimura teaches that carbonated warm water having high concentration of CO<sub>2</sub> is useful in the formation of new blood vessels of an affected site, because the presence of CO<sub>2</sub> at high concentration and warm temperature substantially increased cutaneous blood flow and thermal sensation and consequently increase the number of vascular endothelial cells in the tissue of an affected site.”

“Because carbonated spring water has been used for the treatment of peripheral vascular diseases, due to their potent vasodilation action, they are widely used for vascularization therapy, one of ordinary skill in the art would have motivated to incorporate the

carbonated warm water in the composition advanced by Ritter. Based on the teaching of Nishimura, there is reasonable expectations of successfully preparing stable and effective therapeutic composition for the vascularization therapy, utilizing vasodilation action and increased blood flow volume brought about by carbonated warm water having carbon dioxide to increase the number of newly formed blood vessel at an affected site. In other words, the combination of the cited references provides sufficient information to make and use the invention as claimed.”

Applicants respectfully traverse this rejection for the following reasons.

First, Ritter does not mention carbonated warm water or carbon dioxide concentration and the temperature thereof at all in their specification, and thus Ritter would not have taught or even suggested a vascularization therapy which involves the immersion of the affected site of a peripheral blood vessel in carbonated warm water having a carbon dioxide concentration of at least 700 ppm and a temperature of 33 to 42°C. This is also evident from the above quotation from the Office Action which does not recite carbonated warm water or carbon dioxide concentration and the temperature thereof at all from Ritter. In short, there does not appear to be anything in common between Ritter and the present invention. The passage in Ritter (column 1, lines 19-22); so that “[e]ssentially, all wound healing involves the repair of replacement of damaged tissues including but not limited to skin, muscle, neurologic tissues, bone, soft tissue, internal organs or vascular tissue,” which is not a description of “vascularization therapy” as claimed. It is merely an isolated statement. It cannot be transmitted into a “teaching” if something factually there is not actually disclosed in the reference. As was said in *In re Rosenberger*, 386 F.2d 1015, 1018, 156 USPQ 24, 26 (CCPA 1967), “[t]his appears to be an extremely strained interpretation of the reference which could

be made only by hindsight.” In other words, Ritter does not encompass “vascularization therapy” recited in the Claims of the present invention.

Second, Nishimura simply does not appear to even be intended for a vascularization therapy directly as explained herein above. *See, e.g., In re Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002) (“the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion...”). Nishimura relates that immersing the right forearm of a subject (a healthy male) in carbon dioxide-rich water (1,000 ppm) that was maintained at a temperature of 34°C results in an increase in cutaneous blood flow due to vasodilation, and an elevation of the score on thermal sensation. These physiological effects, *i.e.* an increase in cutaneous blood flow, cutaneous vasodilation, and elevation of the score on thermal sensation in a healthy male are entirely distinct from the “formation of new blood vessels (vascularization)” (see Applicants’ claims). The Office Action, however, attempts to connect the two in the above highlighted and quoted passages from the Office Action, but there is no objective evidence given in Nishimura or the Office Action in support.

It is therefore courteously suggested that the rejection be reconsidered and withdrawn.




U.S. Appln. of Sakakibara et al.  
Appln. No. 10/676,270  
Response to May 23, 2007 Office Action

Attorney Docket: 7412/80657

**Conclusion**

Applicants respectfully solicit favorable reconsideration and a Notice of Allowance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Kendrew H. Colton', is written over a horizontal line.

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